

Appl. No.: 10/795,931
Amendment Dated October 17, 2006
Reply to Office Action of July 18, 2006

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REMARKS/ARGUMENTS

Priority

The Office Action indicates that Applicants' claim for domestic priority under 35 U.S.C. § 119(e) fails for SEQ ID NOS: 7-9. The Office Action asserts that Provisional Application Serial No. 60/165,176, from which Applicants' claim priority for the instant application, does not provide an adequate written description of SEQ ID NOS: 7-9. The Office Action concludes that the instant application is only entitled to the priority date of 13 November 2000.

Applicants note for the record that Provisional Application Serial No. 60/165,176 provides an adequate written description of non-elected SEQ ID NOS: 1-4 because these sequences are fully disclosed therein. Applicants further note that SEQ ID NO: 3 is a partial-length genomic nucleotide sequence of *Dw3-T* allele and that this sequence corresponds to the full-length genomic nucleotide sequence of *Dw3-T* set forth in SEQ ID NOS: 7. Applicants also note that SEQ ID NO: 4 is a partial-length amino acid sequence of the DW3 protein and that this amino acid sequence corresponds to the full-length amino acid sequence of the DW3 protein set forth in SEQ ID NO: 9.

The Objection to the Specification Should Be Withdrawn

The specification has been objected to for failing to indicate the patent number corresponding to U.S. Application No. 09/711,619 in the Cross-Reference to Related Applications section on page 1. At the time of filing of the instant application, a patent had not yet issued from U.S. Application No. 09/711,619, and therefore, Applicants could not provide this patent number at the time of filing.

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To overcome this objection, Applicants have amended the specification to include the patent number as recommended by the Examiner. This amendment to the specification is purely formal in nature and does not introduce new matter.

In view of the amendment to the specification, it is submitted that the objection to the specification should be withdrawn.

Status of the Claims

Claims 1, 5, 19, and 27 have been amended to delete part (c). Applicants have amended these claims without prejudice or disclaimer in the interest of furthering prosecution and not to limit the subject matter of Applicants' claimed invention. Applicants expressly reserve the right to file one or more continuing applications directed to the subject matter deleted from these claims.

Claim 26 has been amended to point out more distinctly that Applicants' claimed methods can be used to produce a sorghum plant this is suitable for use in commercial sorghum production. Support for this amendment can be found throughout the specification, particularly on pages 7-8.

No new matter has been added by way of amendment of the claims.

Claims 1-27 remain pending.

Reexamination and reconsideration of the application as amended are respectfully requested.

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The Objection to Claim 26 Should Be Withdrawn

Claim 26 has been objected to for being an improper dependent claim for failing to limit further the subject matter of the previous claim. The Office Action indicates that the recitation of an intended use, "used in commercial sorghum production", does not appear to limit further claim 25, the claim from which claim 26 depends.

Although Applicants respectfully disagree with this view of the Office Action, Applicants have amended claim 26 to point out more distinctly their claimed invention. As amended, claim 26 further limits the stable dwarf sorghum plant of claim 25 to a stable dwarf sorghum plant that is suitable for use in commercial sorghum production. Accordingly, amended claim 26 is not an improper dependent claim.

In view of the amendment to claim 26 and the remarks, it is submitted that the objection to claim 26 should be withdrawn.

The Rejection of the Claims for Nonstatutory, Double Patenting Should Be Withdrawn

Claims 1-27 have been rejected under the judicially created doctrine of obviousness-type, double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,750,380. Claims 1, 5, 19, 26 and 27 have been amended. This rejection is respectfully traversed.

Applicants submit concurrently herewith a terminal disclaimer compliant with 37 C.F.R. § 1.321(c). In view of the terminal disclaimer and the above remarks, it is submitted that the rejections of the claims under the judicially created doctrine of obviousness-type, double patenting should be withdrawn.

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The Rejections of the Claims Under 35 U.S.C. § 112, First Paragraph, Should Be Withdrawn

Claims 1-27 have been rejected under 35 U.S.C. § 112, first paragraph. Claims 1, 5, 19, 26 and 27 have been amended. This rejection is respectfully traversed.

Written Description

Claims 1-27 have been rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. The Office Action indicates that Applicants describe the sorghum *Dw3* gene exemplified in SEQ ID NOS: 7 and 8, encoding the polypeptide of SEQ ID NO: 9 and a mutation of the *Dw3* gene can lead to dwarfing sorghum. The Office Action asserts, however, that Applicants do not sufficiently describe the genus of molecules encoding a P-glycoprotein that controls plant growth having at least 90% identity to SEQ ID NOS: 7 and 8, other than those directed to a non-elected invention, or other molecules that would hybridize under specified stringent conditions to a nucleotide molecule having the sequence of SEQ ID NOS: 7 or 8. In addition, the Office Action cites § 2163 MPEP as stating that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of making coupled with its function and there is no art-recognized correlation or relationship between the structure of the invention and its function. The Office Action indicates that the art teaches that P-glycoproteins have a wide variety of functions and are not specific to plant growth, citing Martinoia *et al.* ((2002) *Planta* 214:345-355).

Applicants respectfully disagree with the Examiner's position that written description requirement has not been met. The first paragraph of § 112 provides, in pertinent part, that "[t]he specification shall contain a written description of the invention." The Federal Circuit, in discussing the standard for determining compliance with the written description requirement, has provided that "[t]he test for sufficiency of support . . . is whether the disclosure of the application reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter. *Vas-Cath Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir.

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1991) (citing *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 227 U.S.P.Q. 177, 179 (Fed.Cir.1985) (quoting *In re Kaslow*, 217 U.S.P.Q 1089, 1096 (Fed.Cir.1983))).

Applicants have met this standard. The instant specification sets forth that SEQ ID NOS: 7 and 8 encode a P-glycoprotein, DW3, having the amino acid sequence set forth in SEQ ID NO: 9. The specification indicates that plants which were homozygous for the *dw3* allele had a dwarf phenotype relative to wild-type plants. Furthermore, the specification on page 49 discloses that multiple alignment results show that overall *Dw3* is 92% and 91.8% identical to the maize *Br2* gene at the nucleotide level and at the amino acid level, respectively. The BR2 protein is known to have an extensive sequence and structural similarity with the multidrug-resistance (MDR)-like gene-encoded P-glycoproteins and that the BR2 protein shares more than 67% amino acid sequence identity with the protein encoded by the *Arabidopsis* P-glycoprotein gene, *AtPGP1*, which was disclosed by Dudler *et al.* ((1992) *J. Biol. Chem.* 267:5882-5888). See, U.S. Provisional Application Serial No. 60/164,886 entitled "Genes and Methods for Manipulation of Growth" filed November 12, 1999, which was incorporated by reference in the instant specification. Furthermore, those of ordinary skill in the art would be familiar with the teachings of Sidler *et al.* ((1998) *Plant Cell* 10:1623-1636) on *AtPGP1* and the P-glycoprotein encoded thereby. Sidler *et al.* teach that a nucleotide sequence encoding a P-glycoprotein can be used to modify the growth of plants. In particular, Sidler *et al.* teach that antisense expression of an *AtPGP1* nucleotide sequence in transgenic *Arabidopsis* plants can reduce the height of a plant and that overexpression of an *AtPGP1* nucleotide sequence in the sense orientation in transgenic *Arabidopsis* plants can increase the height of the plant.

Amended claims 1, 4, 5, 19, and 27 and their respective dependant claims, recite nucleotide sequences having at least 90% sequence identity to the sequence set forth in SEQ ID NO: 7 and/or 8. The recitation of at least 90% sequence identity is a very predictable structure of the sequences encompassed by the claimed invention. The Examiner is reminded, that the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. 66 Fed. Reg. 1099, 1106 (2000). Satisfactory disclosure of a "representative number" depends on

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whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. 66 Fed. Reg. 1099, 1106 (2000). Applicants submit that the knowledge and level of skill in the art would allow a person of ordinary skill to envision the claimed invention, i.e., a sequence having at least 90% sequence identity to the sequence set forth in SEQ ID NO: 7 or 8.

Furthermore, the description of a claimed genus can be by structure, formula, chemical name, or physical properties. *See Ex parte Maizel*, 27 USPQ2d 1662, 1669 (B.P.A.I. 1992), citing *Amgen v. Chugai*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). A genus of DNAs may therefore be described by means of a recitation of a representative number of DNAs, defined by nucleotide sequence, falling within the scope of the genus, or by means of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997); *see also* Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (2000). The recitation of a predictable structure of at least 90% sequence identity to SEQ ID NO: 7 or 8 is sufficient to satisfy the written description requirement.

An Applicant, however, may also rely upon functional characteristics in the description, provided there is a correlation between the function and structure of the claimed invention. *Id.* (citing *Lilly* at 1568). Specifically, claims 1-27 recite that the claimed sequences encode P-glycoproteins that function to control plant growth. While *Martinoia et al.* may teach that P-glycoproteins have a wide variety of functions, the instant claims are directed nucleotide molecules encoding those P-glycoproteins that function to control plant growth. Furthermore, the instant specification sets forth in detail what is intended by controlling the growth of plants.

Thus, in contrast to the view of the Office Action, the genus of nucleotide molecules encompassed by the claims are defined by relevant identifying physical and functional properties. In fact, the common attributes or features of the elements possessed by the members of the genus is

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that they encode P-glycoproteins that function to control plant growth and share at least 90% sequence identity to SEQ ID NO:7 or 8 or are complements thereof.

In summary, the instant disclosure provides a written description that clearly allows persons of ordinary skill in the art to recognize that Applicants have invented what is claimed. Furthermore, the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. Applicants submit that the relevant identifying physical and chemical properties of the disclosed genus would be clearly recognized by one of skill in the art and consequently, that the Applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus. Accordingly, the rejection of claims 1-27 under 35 U.S.C. §112, first paragraph, for lack of written description should be withdrawn.

Enablement

Claims 1-27 have been rejected under 35 U.S.C. § 112, first paragraph, because the specification while being enabling for an isolated nucleic acid encoding the amino acid of SEQ ID NO: 9 does not reasonably provide enablement for isolated nucleic acids having a nucleotide sequence at least 90% identical to SEQ ID NO: 7 or 8 or hybridizes to said nucleotide sequence under the specified stringent conditions.

The Office Action indicates that Applicants teach that the sorghum *Dw3* gene, exemplified in SEQ ID NOS: 7 and 8, encoding the polypeptide of SEQ ID NO: 9. The Office Action further indicates that Applicants teach a mutation of the *Dw3* gene leads to dwarfing in sorghum. The Office Action, however, asserts that Applicants do not sufficiently teach the genus of nucleotide molecules encoding a P-glycoprotein that controls plant growth having at least 90% identity to SEQ ID NO: 7 or 8, other than those directed to the non-elected invention or other nucleotide molecules that hybridize under specified stringent conditions to SEQ ID NO: 7 or 8. The Office Action asserts that the genus of nucleotide molecules that could be used in a method for modifying the growth of a plant and that encode a P-glycoprotein that functions to

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control growth of a plant is not adequately taught and that the art teaches that P-glycoproteins have a wide variety of functions and are not specific to plant growth, citing Martinoia *et al.* ((2002) *Planta* 214:345-355).

Notwithstanding the teaching of Martinoia *et al.* that P-glycoproteins have a wide variety of functions in plants, Applicants' invention is drawn to nucleotide molecules encoding P-glycoproteins that are capable of functioning to control the growth of a plant. Such nucleotide molecules find use in methods for modifying the growth of plants. The claimed methods involve the expression of the nucleotide molecules in either the sense or antisense orientation and do not depend on use in a particular plant species such as sorghum.

In contrast to the Examiner's conclusions, the specification provides sufficient guidance to make and identify the nucleotide molecules encompassed by the amended claims. In particular, Applicants have provided the nucleotide sequence of SEQ ID NOS: 7 and 8. The claimed nucleotide molecules vary from this sequence by structural parameters (*i.e.*, percent sequence identity to SEQ ID NO:7 or 8). Guidance for determining percent sequence homology is provided in the specification on pages 21-26.

Moreover, the nucleotide molecules of the invention encode P-glycoproteins that are capable of controlling the growth of a plant. Such nucleotide molecules include those that encode fragments and variants of SEQ ID NO: 9 and encode P-glycoproteins that are capable of controlling the growth of a plant. Guidance regarding alterations that allow the nucleotide molecules and polypeptides of the invention to retain biological activity is also provided. See, for example, pages 14-17. And finally, methods for assaying whether the nucleotide molecules are capable of controlling the growth of a plant when expressed therein are known in the art and are also provided in the instant specification. For example, one of skill in the art could transform a plant with a nucleotide sequence encoding P-glycoprotein operably linked in either a sense or antisense orientation to a promoter and produce a transgenic plant using the guidance set forth in the specification on pages 27-39 and 50-54. The transgenic plant can then be assessed for modified growth relative to a wild-type plant by assessing one or more of the growth-related

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phenotypic characteristics that are set forth in the specification, particularly on pages 11-12. Accordingly, based on the guidance in the specification, one of skill in the art would be able to determine which nucleotide sequences are encompassed by the present invention.

The Federal Circuit has repeatedly stated that enablement is not precluded by the necessity for some experimentation, so long as the experimentation needed to practice the invention is not undue. *In re Wands* 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). Furthermore, a considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance in which the experimentation should proceed. *Id.*

Applicants stress that when evaluating the quantity of experimentation required, the court looks to the amount of experimentation required to practice a single embodiment of the invention, rather than the amount required to practice every embodiment of the invention. For example, in *Wands*, the claims at issue were drawn to immunoassay methods using any monoclonal antibody having a binding affinity for HbsAg of at least 10^{-9} M. The PTO had taken the position that the claim was not enabled as it would take undue experimentation to make the monoclonal antibodies required for the assay. The Federal Circuit reversed, and held that the claims were enabled, as the amount of experimentation required to isolate monoclonal antibodies and screen for those having the correct affinity was not undue. *Id.* Clearly, the Federal Circuit did not contemplate that every antibody useful in the methods of the claim must be identified. Rather, the court considered the amount of experimentation required to identify one or a few monoclonal antibodies having the required affinity.

In the instant case, the quantity of experimentation required to practice the invention amounts to two steps, generating a nucleotide sequence having a least 90% sequence identity to SEQ ID NO: 7 and/or 8 and assaying for functional activity.

In summary, ample guidance is therefore provided to allow one of skill in the art to identify the sequences encompassed by claims 1-27. Consequently, contrary to the Examiner's conclusions, the quantity of experimentation necessary and the amount of guidance presented in

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the specification is sufficient to enable the invention as set forth in claims 1-27. Accordingly, the rejection of the claims under 35 U.S.C. § 112, first paragraph, for lack of enablement should be withdrawn.

The Rejections of the Claims Under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn

Claims 21, 22, 25, and 26 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claims 19 and 26 have been amended. This rejection is respectfully traversed.

The Office Action indicates that claims 21, 22, 25, and 26 are indefinite for omitting the essential element of "wherein the nucleic acid molecule encoding the P-glycoprotein is in the antisense orientation." (Office Action of July 18, 2006, p. 9). The Office Action asserts that expression of an antisense transgene product would be essential because these claims require suppression of the endogenous P-glycoprotein gene product to be operable.

Applicants respectfully disagree that the expression of an antisense transgene product is an essential element of the methods of claims 21, 22, 25, or 26. While these claims encompass the expression of an antisense transgene product to suppress the expression of an endogenous gene, Applicants' claimed invention is not limited to the suppressing the expression of an endogenous P-glycoprotein gene by the expression of an antisense transgene. Although those of ordinary skill in the art would be familiar with methods for suppressing the expression of endogenous genes that do not involve antisense transgene expression, the specification teaches, for example, on page 31 that the nucleotide molecules of the present invention can also be used in the sense orientation to suppress the expression of endogenous genes in plants. Accordingly, claims 21, 22, 25, or 26 do not lack an essential element and thus, are not indefinite.

In view of the amendments and remarks, it is submitted that the rejections under 35 U.S.C. § 112, second paragraph, should be withdrawn.

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The Rejection of the Claims Under 35 U.S.C. § 102(b) Should Be Withdrawn

Claims 1-3, 5-7, 10-14, 17-22 and 27 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Sidler *et al.* ((1998) *Plant Cell* 10:1523-1636) taken with the evidence of Fourgoux-Nicol *et al.* ((1999) *Plant Mol. Biol.* 40:857-872). Claims 1, 5, 19, and 27 have been amended. This rejection is respectfully traversed.

The Office Action asserts that Sidler *et al.* discloses an isolated nucleic acid encoding an ABC transporter that controls plant growth and that would hybridize under the specified hybridization conditions of the claims. The Office Action cites Fourgoux-Nicol *et al.* as teaching that under stringent hybridization conditions, a wide variety of nucleic acids having low sequence similarity can be isolated.

Applicants respectfully disagree with the position of the Office Action that the isolated nucleic acid of Sidler *et al.* would hybridize under the specified conditions to SEQ ID NO: 7 and/or 8. In the interest of furthering prosecution of the instant application and not to limit the scope of their claimed invention, Applicants have amended claims 1, 5, 19, and 27 to delete the Markush member that is directed to hybridizing sequences. Accordingly, this rejection of the claims is obviated.

In view of the amendments and remarks, it is submitted that the rejection under 35 U.S.C. § 102(b) should be withdrawn.

The Rejection of the Claims Under 35 U.S.C. § 103(a) Should Be Withdrawn

Claims 8, 9, 15, 16, and 23-26 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Sidler *et al.* ((1998) *Plant Cell* 10:1523-1636) in view of Fourgoux-Nicol *et al.* ((1999) *Plant Mol. Biol.* 40:857-872). Claims 1, 5, 19, 26 and 27 have been amended. This rejection is respectfully traversed.

The Office Action actions indicates that the teachings of Sidler *et al.* and Fourgoux-Nicol *et al.* are the same ones discussed in the Office Action for the rejections of the claims under

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under 35 U.S.C. § 102(b). The Office Action indicates that Sidler *et al.* does not teach transformation of monocot plants with a P-glycoprotein encoding nucleic acid that controls plant growth but that it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to isolate other P-glycoprotein encoding nucleic acids that control plant growth and transform the homologous plant with an antisense to produce a dwarfed plant by modifying the teaching of Sidler *et al.*

As discussed above, Applicants have amended claims 1, 5, 19, and 27 to delete the Markush member that is directed to hybridizing sequences. As amended, the claims are not obvious in view of Sidler *et al.* and Fourgoux-Nicol *et al.* because these references do not teach or even suggest the nucleotide molecules encompassed by the amended claims.

In view of the amendments and remarks, it is submitted that the rejections under 35 U.S.C. § 103 should be withdrawn.

CONCLUSIONS

In view of the above amendments and remarks, Applicants submit that the rejections of the claims under 35 U.S.C. §§ 102, 103, and 112 and for nonstatutory, obviousness-type, double patenting are overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited.

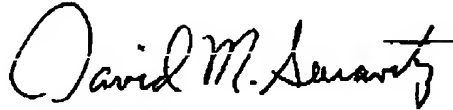
If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required

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therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,




David M. Saravitz
Registration No. 55,593

Customer No. 29122
ALSTON & BIRD LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
Tel Raleigh Office (919) 862-2200
Fax Charlotte Office (704) 444-1111

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the US Patent and Trademark Office at Fax No. (571) 273-8300 on the date shown below.


Karyn Grimm

October 17, 2006
Date